GAVILYTE - N - polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride powder, for solution

GAVIS Pharmaceuticals, LLC

Rx Only

DESCRIPTION

GaviLyte –N is a white powder for reconstitution containing 420 g polyethylene glycol 3350, 5.72 g sodium bicarbonate, 11.2 g sodium chloride, 1.48 g potassium chloride and one 2 g flavor pack (optional). When dissolved in water to a volume of 4 liters, GaviLyte –N (PEG-3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution) is an isosmotic solution, for oral administration, having a pleasant mineral water taste. GaviLyte –N is administered orally or via nasogastric tube as a gastrointestinal lavage. GaviLyte –N Flavor Pack is available in lemon flavor. This preparation can be used without the addition of a GaviLyte –N Flavor Pack.

CLINICAL PHARMACOLOGY

GaviLyte –N induces a diarrhea which rapidly cleanses the bowel, usually within four hours. The osmotic activity of polyethylene glycol 3350 and the electrolyte concentration result in virtually no net absorption or excretion of ions or water. Accordingly, large volumes may be administered without significant changes in fluid or electrolyte balance.

INDICATIONS AND USAGE

GaviLyte –N is indicated for bowel cleansing prior to colonoscopy.

CONTRAINDICATIONS

GaviLyte –N is contraindicated in patients known to be hypersensitive to any of the components. GaviLyte –N is contraindicated in patients with ileus, gastrointestinal obstruction, gastric retention, bowel perforation, toxic colitis or toxic megacolon.

WARNINGS

GaviLyte –N Flavor Pack is for use only in combination with the contents of the accompanying 4 liter container. No additional ingredients, e.g. flavorings, should be added to the solution. GaviLyte –N should be used with caution in patients with severe ulcerative colitis. Use of GaviLyte –N in children younger than 2 years of age should be carefully monitored for occurrence of possible hypoglycemia, as this solution has no caloric substrate. Dehydration has been reported in 1 child and hypokalemia has been reported in 3 children.

PRECAUTIONS

General

Patients with impaired gag reflex, unconscious, or semiconscious patients, and patients prone to regurgitation or aspiration should be observed during the administration of GaviLyte –N, especially if it is administered via nasogastric tube. If a patient experiences severe bloating, distention or abdominal pain, administration should be slowed or temporarily discontinued until the symptoms abate. If gastrointestinal obstruction or perforation is suspected, appropriate studies should be performed to rule out these conditions before administration of GaviLyte –N.

Information for Patients

GaviLyte –N produces a watery stool which cleanses the bowel before examination. Prepare the solution according to the instructions on the bottle. It is more palatable if chilled. For best results, no solid food should be consumed during the 3 to 4 hour period before drinking the solution, but in no case should solid foods be eaten within 2 hours of taking GaviLyte –N.

Adults drink 240 mL (8 oz.) every 10 minutes. Continue drinking until the watery stool is clear and free of solid matter. This usually requires at least 3 liters. Any unused portion should be discarded. Pediatric patients (aged 6 months or greater) drink 25 mL/kg/hour. Continue drinking until the watery stool is clear and free of solid matter. Any unused portion should be discarded. Rapid drinking of each portion is better than drinking small amounts continuously. The first bowel movement should occur approximately one hour after the start of GaviLyte –N administration. You may experience some abdominal bloating and distention before the bowels start to move. If severe discomfort or distention occur, stop drinking temporarily or drink each portion at longer intervals until these symptoms disappear.

Use of GaviLyte –N in children younger than 2 years of age should be carefully monitored for occurrence of possible hypoglycemia, as this solution has no caloric substrate. Dehydration has been reported in 1 child and hypokalemia has been reported in 3 children.

Drug Interactions

Oral medication administered within one hour of the start of administration of GaviLyte –N may be flushed from the gastrointestinal tract and not absorbed.

Carcinogenesis, Mutagenesis, Impairment of Fertility
Carcinogenic and reproductive studies with animals have not been performed.

Pregnancy
Category C. Animal reproduction studies have not been conducted with GaviLyte –N. It is also not known whether GaviLyte –N can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. GaviLyte –N should be given to a pregnant woman only if clearly needed.

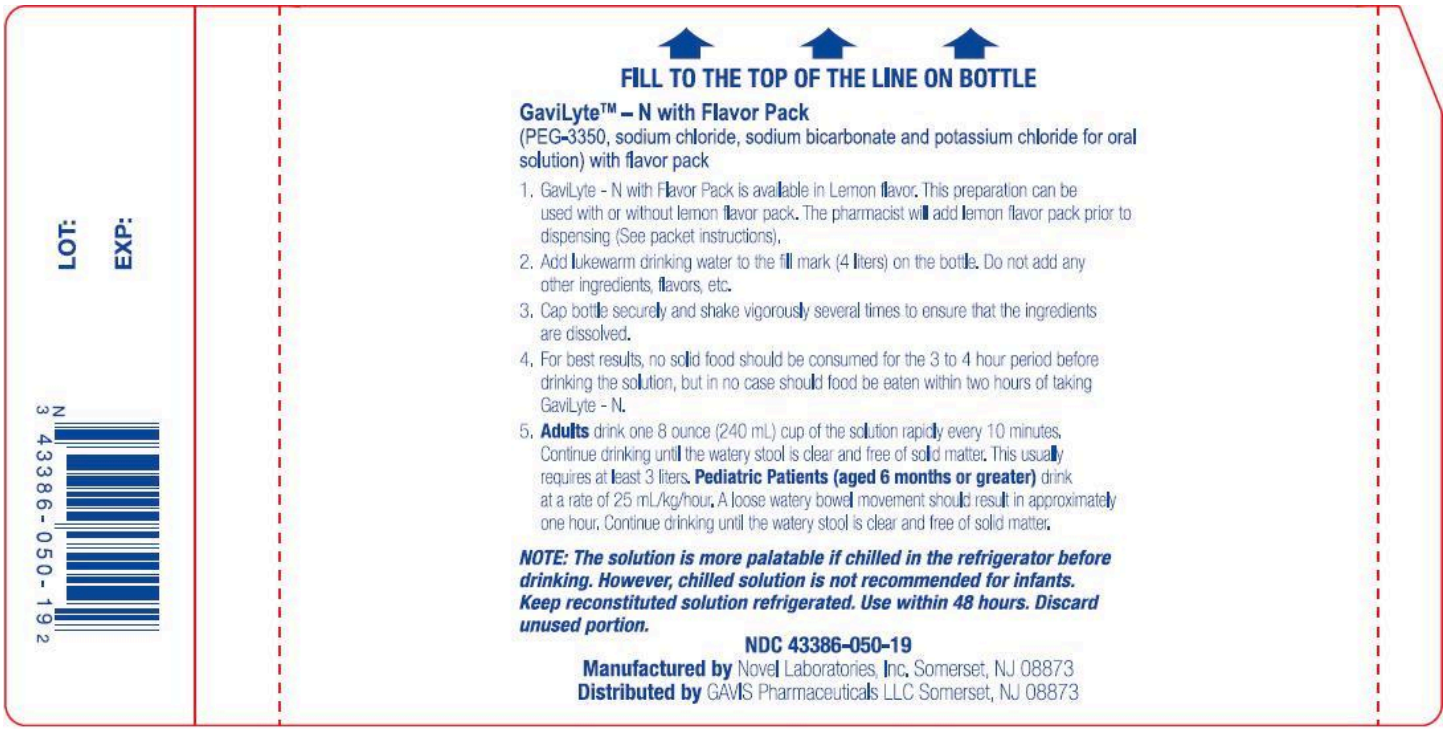
Pediatric Use
Safety and effectiveness of GaviLyte –N in pediatric patients aged 6 months and older is supported by evidence from adequate and well-controlled clinical trials of GaviLyte –N in adults with additional safety and efficacy data from published studies of similar formulations.

ADVERSE REACTIONS
Nausea, abdominal fullness and bloating are the most common adverse reactions (occurring in up to 50% of patients) to administration of GaviLyte –N. Abdominal cramps, vomiting and anal irritation occur less frequently. These adverse reactions are transient and subside rapidly. Isolated cases of urticaria, rhinorrhea, dermatitis and (rarely) anaphylactic reaction have been reported which may represent allergic reactions. Published literature contains isolated reports of serious adverse reaction following the administration of PEG-ELS products in patients over 60 years of age. These adverse events include upper GI bleeding from Mallory-Weiss Tear, esophageal perforation, asystole, sudden dyspnea with pulmonary edema, and "butterfly-like" infiltrate on chest X-ray after vomiting and aspirating PEG.

DOSAGE AND ADMINISTRATION
GaviLyte –N is usually administered orally, but may be given via nasogastric tube to patients who are unwilling or unable to drink the solution. Ideally, the patient should fast for approximately three or four hours prior to GaviLyte –N administration, but in no case should solid food be given for at least two hours before the solution is given.
Oral administration
Adults: At a rate of 240 mL (8 oz.) every 10 minutes, until the rectal effluent is clear or 4 liters are consumed. **Pediatric Patients(aged 6 months or greater):** At a rate of 25 mL/kg/hour, until the rectal effluent is clear. Rapid drinking of each portion is preferred to drinking small amounts continuously. **Nasogastric tube administration:Adults:** At a rate of 20 to 30 mL per minute (1.2 to 1.8 liters per hour). **Pediatric Patients(aged 6 months or greater):** At a rate of 25 mL/kg/hour, until the rectal effluent is clear. The first bowel movement should occur approximately one hour after the start of GaviLyte –N administration. Ingestion of 4 liters of GaviLyte –N solution prior to gastrointestinal examination produces satisfactory preparation in over 95% of patients.
Various regimens have been used. One method is to schedule patients for examination in midmorning or later, allowing the patients three hours for drinking and an additional one hour period for complete bowel evacuation. Another method is to administer GaviLyte –N on the evening before the examination.
Preparation of the solution: GaviLyte –N solution is prepared by filling the container to the 4 liter mark with water and shaking vigorously several times to insure that the ingredients are dissolved. Dissolution is facilitated by using lukewarm water. The solution is more palatable if chilled before administration. However, chilled solution is not recommended for infants. The reconstituted solution should be refrigerated and used within 48 hours. Discard any unused portion.

HOW SUPPLIED
GaviLyte –N with Flavor Pack is supplied in a disposable jug, in powdered form, for oral administration as a solution following reconstitution. Each jug has an attached lemon flavor pack, in powdered form, for the addition of the flavor pack by the pharmacist prior to dispensing.
GaviLyte –N with Flavor Pack: PEG 3350 420 g, sodium bicarbonate 5.72 g, sodium chloride 11.2 g, potassium chloride 1.48 g and lemon flavor pack 2 g (optional). When made up to 4 liters volume with water, the solution contains PEG-3350 31.3 mmol/L, sodium 65 mmol/L, chloride 53 mmol/L, bicarbonate 17 mmol/L and potassium 5 mmol/L.
STORAGE: Store in sealed container at 25°C. When reconstituted, keep solution refrigerated. Use within 48 hours. Discard unused portion.
NDC 43386-050-19
Manufactured by:
Novel Laboratories, Inc.
Somerset, NJ 08873
Distributed by:
GAVIS Pharmaceuticals, LLC
Somerset, NJ 08873
GLB-050-4L-02

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



LOT:

EXP:

3 43386-050-19 2

FILL TO THE TOP OF THE LINE ON BOTTLE

GaviLyte™ – N with Flavor Pack

(PEG-3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution) with flavor pack

1. GaviLyte - N with Flavor Pack is available in Lemon flavor. This preparation can be used with or without lemon flavor pack. The pharmacist will add lemon flavor pack prior to dispensing (See packet instructions).
2. Add lukewarm drinking water to the fill mark (4 liters) on the bottle. Do not add any other ingredients, flavors, etc.
3. Cap bottle securely and shake vigorously several times to ensure that the ingredients are dissolved.
4. For best results, no solid food should be consumed for the 3 to 4 hour period before drinking the solution, but in no case should food be eaten within two hours of taking GaviLyte - N.
5. **Adults** drink one 8 ounce (240 mL) cup of the solution rapidly every 10 minutes. Continue drinking until the watery stool is clear and free of solid matter. This usually requires at least 3 liters. **Pediatric Patients (aged 6 months or greater)** drink at a rate of 25 mL/kg/hour. A loose watery bowel movement should result in approximately one hour. Continue drinking until the watery stool is clear and free of solid matter.

NOTE: The solution is more palatable if chilled in the refrigerator before drinking. However, chilled solution is not recommended for infants. Keep reconstituted solution refrigerated. Use within 48 hours. Discard unused portion.

NDC 43386-050-19

Manufactured by Novel Laboratories, Inc. Somerset, NJ 08873

Distributed by GAVIS Pharmaceuticals LLC Somerset, NJ 08873

DOSAGE AND ADMINISTRATION

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Oral administration

Adults: At a rate of 240 mL (8 oz.) every 10 minutes, until the rectal effluent is clear or 4 liters are consumed. **Pediatric Patients (aged 6 months or greater):** At a rate of 25 mL/kg/hour, until the rectal effluent is clear. Rapid drinking of each portion is preferred to drinking small amounts continuously. **Nasogastric tube administration: Adults:** At a rate of 20 to 30 mL per minute (1.2 to 1.8 liters per hour). **Pediatric Patients (aged 6 months or greater):** At a rate of 25 mL/kg/hour, until the rectal effluent is clear.

The first bowel movement should occur approximately one hour after the start of GaviLyte – N administration. Ingestion of 4 liters of GaviLyte – N solution prior to gastrointestinal examination produces satisfactory preparation in over 95% of patients. Various regimens have been used. One method is to schedule patients for examination in midmorning or later, allowing the patients three hours for drinking and an additional one hour period for complete bowel evacuation. Another method is to administer GaviLyte – N on the evening before the examination.

Preparation of the solution: GaviLyte – N solution is prepared by filling the container to the 4 liter mark with water and shaking vigorously several times to insure that the ingredients are dissolved. Dissolution is facilitated by using lukewarm water. The solution is more palatable if chilled before administration. However, chilled solution is not recommended for infants. The reconstituted solution should be refrigerated and used within 48 hours. Discard any unused portion.

HOW SUPPLIED

GaviLyte – N with Flavor Pack is supplied in a disposable jug, in powdered form, for oral administration as a solution following reconstitution. Each jug has an attached lemon flavor pack, in powdered form, for the addition of the flavor pack by the pharmacist prior to dispensing.

GaviLyte – N with Flavor Pack: PEG-3350 420g, sodium bicarbonate 5.72g, sodium chloride 11.2g, potassium chloride 1.48g and lemon flavor pack 2g (optional). When made up to 4 liters volume with water, the solution contains PEG-3350 31.3 mmol/L, sodium 65 mmol/L, chloride 53 mmol/L, bicarbonate 17 mmol/L and potassium 5 mmol/L.

STORAGE: Store in sealed container at 25°C. When reconstituted, keep solution refrigerated. Use within 48 hours. Discard unused portion.

NDC 43386-050-19

Manufactured by:
Novel Laboratories, Inc.
Somerset, NJ 08873

Distributed by:
GAVIS Pharmaceuticals LLC
Somerset, NJ 08873

GLB-050-L-02

NDC # 43386-050-19

FILL TO THE TOP OF THE LINE ON BOTTLE

To Pharmacist:
Patient instructions are on base label. Discard unused flavor pack.
Package insert may be removed before dispensing.

PULL DOWN TO OPEN

GaviLyte™ - N

PEG-3350, Sodium Chloride, Sodium Bicarbonate and Potassium Chloride for Oral Solution

with Flavor Pack

When reconstituted with water to a volume of 4 liters, this solution contains PEG-3350 31.3 mmol/L, sodium 65 mmol/L, chloride 53 mmol/L, bicarbonate 17 mmol/L and potassium 5 mmol/L

Each disposable jug contains, in powdered form:

Polyethylene Glycol 3350	420g
Sodium bicarbonate	5.72g
Sodium chloride	11.2g
Potassium chloride	1.48g

Rx only

GAVIS™ PHARMACEUTICALS

GaviLyte™ – N with Flavor Pack

(PEG-3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution) with flavor pack

GAVIS Pharmaceuticals LLC

Rx Only

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